

Updated October 2014

## General Overview of the Food Safety Modernization Act

*Author: Shaun Kennedy and Kaylee Myhre Errecaborde, College of Veterinary Medicine, University of Minnesota.*

*Reviewed by a multidisciplinary team from the College of Veterinary Medicine and the School of Public Health; University of Minnesota.*

### Summary of Findings:

- Despite the US having one of the safest food supplies in the world, foodborne illness continues to sicken nearly 48 million people per year and accounts for over 3000 deaths in the US.
- The Food Safety Modernization Act (FSMA), passed by congress in 2011, represents the first major reform to the US Food and Drug Administration (FDA) food safety authority in over 70 years.
- FSMA requires enhanced regulation of produce from farm to sale and other FDA regulated foods from processing to sale and introduces food defense requirements.
- FSMA alters the role of FDA in food Safety through 5 key changes:
  - A shift of focus from reaction to prevention including preventing intentional contamination.
  - More authority to inspect and assure compliance with inspection frequencies based on risk.
  - Mandatory recall authority.
  - Authorities to strengthen import safety to assure that US food safety standards are met.
  - Stronger partnerships with other government agencies and private entities.

---

### Background

Despite the United States (US) having one of the safest food supplies in the world, the US Centers for Disease Control and Prevention estimates that each year nearly 48 million people (roughly 1 in 6 Americans) are sickened, 128,000 are hospitalized, and 3,000 people die from preventable foodborne illnesses.<sup>1</sup> In recent years, high profile and deadly outbreaks of foodborne illness have fueled the interest of policy makers and their constituents in improving food safety.

- (2008/09) An outbreak of *Salmonella* Typhimurium in peanut products sickened over 700 people in forty-six states and may have contributed to 9 deaths. In total, 398 products from 361 companies were recalled and FDA is actively pursuing a criminal case.<sup>2</sup>
- (2008) The melamine milk scandal in China caused the death of 6 infants, sickened over 300,000 people, and drew intense international criticism.<sup>3</sup>
- (2010) Five hundred million eggs produced in Iowa were recalled due to suspected *Salmonella* Enteritidis contamination, sickening over 1,900 people.<sup>4</sup>
- (2012) Cantaloupe contaminated with *Listeria monocytogenes* sickened at least 147 people, killed more than 30, and was one of the deadliest foodborne illness outbreaks in US history. The owners have since pled guilty to violating federal law.<sup>5</sup>

In response to such events, the US Congress has passed historic new legislation, the first major reform of the US Food and Drug Administration (FDA) food safety authority in over 70 years. The Food Safety Modernization Act (FSMA) was signed into law by President Obama in 2011. The law is intended to shift FDA focus to better protect public health by *preventing* food safety issues rather than *reacting* to outbreaks. FSMA is a large piece of legislation intended to build a new proactive federal food safety system. The regulations continue to evolve with each new event and with the continued engagement of the FDA with stakeholders including, states and the food industry.

### **What are the key changes integrated into FSMA?**

The FDA has regulatory authority to ensure the safety of about 80% of all domestic and imported foods, excluding most meats, poultry, and processed egg products regulated by the US Department of Agriculture (USDA). Specifically, FSMA enhances regulation of *produce* from farm to sale and *all other FDA-regulated foods* from processing to sale. FSMA alters the role of the FDA in food safety through five key changes. First, FSMA shifts the FDA role from reactive to preventative by requiring the FDA to mandate comprehensive, prevention-based controls across the food supply and providing new authority to prevent intentional contamination. Second, FSMA grants the FDA more authority to inspect and ensure compliance through mandated inspections with frequencies based on risk. Third, FSMA grants the FDA mandatory recall authority, enabling prompt response to problems when they occur. Fourth, FSMA enables the FDA to better address major weaknesses in import safety and to ensure that US food safety standards are being met.<sup>6</sup> Fifth, FDA will strengthen partnerships with other food agencies and private entities and enhance the rule making process. To facilitate implementation of FSMA, Congress established specific compliance deadlines for the FDA within the legislation. These deadlines were recently further modified in an agreement by FDA in federal court. At present, three proposed regulations are already in effect while seven others are advancing through the federal rule-making process.

### **What will be the general requirements for all food producers and processors?**

All food producers (i.e., food manufacturers, processors, packers, and distributors), except USDA regulated meat, poultry, and processed egg producers, will be required to comply with general FSMA requirements unless otherwise exempted. These requirements are to:

- Register with the FDA biannually
- Create a Food Safety Plan with science-based preventive controls based on a hazard analysis
- Create a Food Defense Plan with science-based mitigation strategies based on a vulnerability assessment
- Promptly report any foods that may cause adverse health effects to the Reportable Food Registry
- For dairy farms, except properly exempted ‘very small’ dairy farms, compliance is required with some portions of the Intentional Adulteration Rule (actual requirements will be in the final rule)

### **Why are dairy farms included, and some other food processors excluded, in FSMA?**

Dairy farms, of which Minnesota was ranked 6<sup>th</sup> largest dairy state in the US, have been specifically included in FSMA’s Intentional Adulteration rule; no other types of farms are included. Other industries, such as seafood, juice, and canned goods, have been exempted from parts of FSMA as a result of already being FDA-regulated by Hazard Analysis and Critical Control Point (HACCP) programs. The dairy industry does not participate in these programs and is instead FDA-regulated against *accidental* contamination through the Pasteurized Milk Ordinance (PMO). Dairy farms have been included as vulnerable and risk assessments have determined that *intentional* terrorist contamination at dairy farms have the potential to cause significant illness or death.

### **Summary**

Everyone has a role in the “food safety continuum”. The job of the FDA is to regulate food safety; it is the responsibility of each company to ensure the safety of their food products until the consumer takes over responsibility. FSMA is in the midst of a lengthy rule making and guidance process, which means the FDA is turning the bill passed by Congress into actual rules and regulations and related guidance documents. Guidance documents, while not regulations, can be equally as important to industry as formal regulations. Failing to follow issued guidance could significantly increase liability risk in the event of a food safety incident. Most proposed regulations are released and then open for public comment. In hopes of making the final regulations beneficial, it is important that stakeholders included in this legislation are active and vocal about their needs.

For the most recent updates and current implementation status, visit the FDA FSMA website:  
<http://www.fda.gov/Food/GuidanceRegulation/FSMA/default.htm>

## References

1. Estimates of foodborne illnesses in the United States. <http://www.cdc.gov/foodborneburden>. January 8, 2014. *Accessed 06/2014*.
2. Multistate Outbreak of Salmonella Typhimurium Infection Linked to Peanut Butter, *Final Update*. <http://www.cdc.gov/salmonella/typhimurium/update.html>. May 11, 2010. *Accessed 06/2014*.
3. *Food Safety News*. Provides a complete accounting of foodborne illness outbreaks. <http://www.foodsafetynews.com>. *Accessed 06/2014*.
4. Salmonella Enteritidis Outbreak in Shell Eggs. <http://www.fda.gov/food/recallsoutbreaksemergencies/outbreaks/ucm222684.htm>. November 30, 2010. *Accessed 06/2014*.
5. Multistate Outbreak of Listeriosis Linked to Whole Cantaloupes from Jensen Farms, CO, *Final Update*. <http://www.cdc.gov/listeria/outbreaks/cantaloupes-jensen-farms/082712>. August 27, 2012. *Accessed 06/2014*.
6. Johnson R., Food safety issues for the 112th congress, Congressional Research Service report. February 10, 2010.